

EXTENDING THE LIFE OF A PATENT IN THE UNITED STATES

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The patent laws of the United States allow for the grant of patent term extensions for delays related to the issuance of the patent under two circumstances--for delays that occur before the grant of the patent and for those that occur after the grant of the patent, but before its expiration.

Additionally, a lesser-known extension of the patent term is available through a private patent extension, under which the US Congress, with the approval of the President, passes a private law to explicitly extend the term of a specific patent.

In 1994, the most recent changes to the US patent laws affecting patent term extensions were passed in connection with the Uruguay Round Agreements Act (URAA), the implementing legislation for the General Agreement on Trade and Tariffs (GATT). Previous to the passage of the URAA, the most noteworthy provisions in US patent law allowing for the extension of patent protections were under the Omnibus Trade and Competitiveness Act of 1988 and the Drug Price Competition and Patent Term Restoration Act of 1984 (the Drug Price-Patent Term Act).

The types of products for which US patent laws permit extensions vary depending upon the provision under which the patentee seeks the extension. Under the URAA, any product, where patent issuance was delayed due to an interference proceeding, a secrecy order, or due to appellate review, qualifies for an extension of its patent term, not to exceed five years. Conversely, patent term extensions under the Drug Price-Patent Term Act are restricted to drug products, or any medical device, food additive, or colour additive subject to regulation under the Federal Food, Drug, and Cosmetic Act. In 1988, the Drug Price-Patent Term Restoration Act was amended by the Generic Animal Drug and Patent Term Restoration Act of 1988 to include animal drugs and veterinary biological products. [PL No 100-670, § 201, 102 Stat. 5666 (1988).]

The Drug Price-Patent Term Act allows an extension for qualifying patents, not to exceed five years. The provisions related to an additional exclusionary period under this Act, however, contemplate extensions only for those delays that arise after the patent's issuance. Thus, for patents qualifying for an extension under the Drug Price-Patent Term Act, its extension provisions may be additive with those under the URAA and, thus, may allow for up to an additional 10 year exclusionary period on such patents. What follows is an overview of the relevant provisions of the laws of the United States under which patent term extensions can be obtained, the way in which these provisions operate and the flexibility of obtaining such extensions.

Extending Patent Terms Under the URAA

Extension of patent terms due to regulatory delay

On June 8 1995, the URAA provisions concerning patent terms and patent extensions became effective. [PL No 103-465, Title V, § 534, 108 Stat. 4990 (1994) codified at 35 USC § 154]. The URAA's purpose was to harmonize the patent terms of the United States with the rest of the world. The Act's provisions work to compensate the patent owner for delays that often occur prior to and in connection with patent issuance and apply to all patents that meet the requirements of the section, regardless of the subject matter of the patent.

If delay is caused prior to issuance and is due to an interference proceeding under 35 USC § 135(a) or because it is subject to secrecy orders under 34 USC § 181 (orders issued pursuant to US Government claim of property interest in or national security concerns about the subject of the patent) the patentee can apply for an extension equal to the period of the delay, not to exceed five years.

Similarly, in the case of an issuance delayed due to review by the Board of Patent Appeals and Interferences or by a federal court, the patentee may receive an extension of the patent term, not to exceed five years. Patents that are subject to a terminal disclaimer due to the issue of another patent claiming subject matter that is not patentably distinct from that under appellate review are not eligible for the extension.

Calculation of the time period for delays due to appellate review are subject to 35 USC § 154(b)(3) which provides that the extension period includes the earliest date of filing for an appeal under 35 USC § 134 or § 141, or commencement of an action under 35 USC § 145 and the latest date of a final decision in favour of the applicant [35 U.S.C. § 154(b)(3)(A)]. Theoretically, the beginning and ending date could exceed the five year extension period allowed under this section. In such cases, patents facing conditions that would otherwise qualify for an extension greater than five years will be limited to a five year extension under the legislation.

Reductions in the outer bounds of the extension term occur for those periods of the appellate review period that occur before the expiration of three years from the filing date of the application for patent and for that period of time during which the applicant did not act with due diligence. Finally, all extensions granted under 35 USC § 154 are subject to the five year limitation, thus rendering the provisions for extensions under interference and secrecy order delays and those for delays due to appellate review additive for purposes of calculating patent term extensions under this section. A patent, therefore, that may be subject to both a secrecy order and an appellate review would be limited to a five year extension, even in the event that the two proceedings caused delay greater than five years.

Patent term extension for existing patents under the URAA

Prior to passage of the URAA, a US patent enjoyed a life of 17 years from the date the patent issued. With the passage of the URAA, the United States instituted a patent term of 20 years, beginning the date on which the patent issued and ending 20 years from the date on which the application for patent was filed. The passage of this legislation effectively has created a one time, automatic patent term extension for existing patents.

Those patents in force as of December 8 1994, or for which application had been made by June 8 1995, and are then issued, receive a patent term that is the greater of the 20-year term or 17 years from grant, subject to any terminal disclaimers. [35 U.S.C. § 154(c)(1).] An automatic extension of the patent term results for those patents in which prosecution took less than three years from the date of filing to the date of issuance.

Extensions For Food and Drug Related Products

Operation of the extension provisions

The Drug Price Competition and Patent Term Restoration Act of 1984 (the Drug Price Patent Term Act) amended 35 USC § 156 to provide for the extension of the normal 17 year patent term of a product, use or process patent if the product which is the subject of the patent is required by Federal law to be approved before it is commercially marketed [PL No 98-417, (1984)]. The Act was passed in recognition of the fact that both the U.S. Food and Drug Administration (FDA) and the US Department of Agriculture (USDA) conduct extensive reviews of human and animal drug applications to determine the safety and efficacy of the drugs or products, including the submission of several years of test data prior to approving a drug for sale and use in the US.

Prior to the enactment of the Drug Price-Patent Term Act, surveys demonstrated that from 1966 to 1979, the effective life of a patent which required regulatory review fell from 13.6 years to 9.5 years. Later studies indicate that the mean effective life fell further until less than one-half of the original patent term remained after regulatory approval. The Act amended 35 USC § 156 with the underlying purpose to recover the time lost to the regulatory approval process.

While approval is required, it may be obtained either before or after patent issuance. However, a patent holder may only obtain an extension for a patent that has already issued. If a patent issues during the regulatory review process, notwithstanding the extension provisions under the URAA, a patent holder may only recover the period of review that occurred after issuance of the patent. Consequently, the patent holder may not enjoy any benefits from the patent because regulatory approval must be obtained prior to marketing the product in the United States [Scott Woolley, Regulatory Delays Hurt Patent Holders, *WALL STREET JOURNAL*, December 19 1991, at B1].

The term "patent term extension" is actually a misnomer in the context of extensions granted for regulatory review delays under 35 USC § 156, because the extension does not actually extend the patent term [interview with Karin Tyson, Special Legal Advisor, Office of Petitions, United States Patent and Trademark Office, Arlington, Virginia

(October 8 1996)]. As patent claims are often broader than the uses for which a product was approved, the effect of 35 USC § 156 is to provide an additional exclusion period for a particular product, method of manufacturing, or use of a product. The extension, then, is limited to the uses for which that particular product or method was originally approved and for which the patent claimed.

The type of products permitted to obtain an extension under the Drug Price-Patent Term Act are restricted. The only products that qualify for the extension are drug products defined as "the active ingredient of . . . new drug, antibiotic drug, or human biological product" as defined in the Food, Drug, and Cosmetic Act or the Public Health Service Act, medical devices, food additives, or colour additives subject to regulation under the Food, Drug, and Cosmetic Act, and certain new animal drugs or veterinary biological products. In part, Congress has selected these products because they are subjected to a regulatory review period as defined in 35 USC § 156 (g).

The US courts will construe this regulatory review period very narrowly. Consider that where a medical device could be offered for sale only after passing through a feasibility phase, an applied research phase, a development phase, and a market introduction phase with the FDA, a US court found that this process did not qualify as a regulatory review period within the scope defined by the statute and therefore failed to qualify the medical device for an extension under 35 USC § 156(f) [*Baxter Diagnostics Inc v AVL Scientific Corp*, 798 F Supp 612 (CD Calif 1992)].

The legislation does work to prevent any one patent holder from obtaining patent extensions on multiple patents related to the same product. [35 U.S.C. § 156(c)(4).] Where the approved product is the subject of several patents as a result of filing continuation, continuation-in part, divisional or otherwise related patent applications, each of which discloses the approved product and its approved use, then only the earliest issued patent is eligible for an extension.

The legislation does provide an exception to the rule, however. Where the earlier issued product patent does not identically disclose or describe the approved product and the holder of each of the two product patents has never been (and must never become) the holder of the other patent, then the product patent can be extended even though the approved product is also claimed in another product patent which has been extended or which has an earlier issuance date. The legislative history explains that the exception was included to prevent an earlier issued patent which claims a broad genus of compounds from blocking the possible extension of a later issued patent claiming a specific member of that genus where neither patent holder had a choice as to which patent to extend.

To date, applications have been filed seeking the extension of patent terms for human pharmaceutical products requiring FDA regulatory review. However, no applications for patent term extension have yet been received for patents that required the regulatory approval of the USDA [interview with Karin Tyson].

With the passage of the URAA, those patents that had been granted an additional exclusionary period under 35 USC § 156 also may qualify to receive an extension of their original patent term of 17 years to the new 20 year term. The two types of extensions are properly tacked, except for those patents kept in force on June 8 1995 solely because of a patent term extension [*Merck & Co Inc v Kessler*, 80 F3d 1543 (Fed. Cir. 1996)]. Despite objections to the extension by both the USPTO and the FDA, the courts held that, as the transitional provisions of the URAA applied only to previously issued patents, this was indication enough that no differentiation in issued patents with later issued patents was intended by the statute. The plain language of the statute required such an outcome.

In response to the outcome of the *Merck* case, Congress proposed two bills that would change the URAA provisions-- in the House of Representatives, HR 359 and in the Senate S 284. Neither bill was reported out of committee and both have died with the close of the fall legislative session. These bills were generally contrary to URAA agreements on intellectual property law, and were not supported by most US industries.

[TABLE 1: CALCULATION OF LENGTH OF PATENT TERM EXTENSION FOR A HUMAN DRUG PRODUCT. See Appendix]

Patent expiration--extension of patent terms and interim extensions

Because an applicant may obtain only one patent term extension related to delays in the regulatory approval process, even if the patent covers multiple products, the applicant must select a specific use or product for which the extension is sought. Additionally, the law prohibits any patented product or method that has previously received an extension due to such delays to receive another extension that would be tacked with the first. The patent extension will be limited to the one use, product or process for which the patent holder seeks the extension and with a few exceptions will be granted for only the first permitted commercial marketing or use of the product under which the regulatory review period occurred. Consequently, the patent's exclusionary period may expire with respect to all but one of the products or processes for which protection was originally granted. In seeking the patent term extension, the applicant should be certain that the regulatory period has ended prior to applying for an extension, otherwise the application will be rejected.

A patent may not have its term extended after the termination of the patent term, therefore failure to file an application will result in the expiration of the patent. To protect a patent that has not yet received regulatory approval, the patent holder may apply for an interim extension of the patent term if he believes that the relevant regulatory review period will exceed the term of the patent. The application for an interim extension may not be filed until the six month period prior to the expiration of the patent, neither may the application be filed any later than 15 days before the expiration of the patent. An applicant may not apply for more than four interim extensions and each extension may be for no more than one year.

Application disclosure requirements and the interplay between the USPTO and the regulatory agencies

In order to obtain an extension under 35 USC § 156, the applicant must disclose information which indicates that a patent term extension is appropriate for the patent in question. The application must be submitted within 60 days of receiving regulatory approval. The deadline is very strict and failure to comply will result in the denial of the application [interview with Karin Tyson].

For example, an application deadline was missed where patent holders, who had obtained FDA approval, waited to file their application until approval was granted by the Drug Enforcement Agency for the same narcotic pharmaceutical. As a result of the missed deadline, the patent holders were precluded from receiving an extension for the regulatory delays attendant with the approval of the patent for marketing. The 60 day period began when the FDA granted its approval of the product [*Unimed Inc v Quigg*, 888 F2d 826, 12 USPQ2d 1644 (Fed Cir 1989)].

After filing the application, it is subject to extensive review by the USPTO, as well as by the respective regulatory agencies from which the patent holder seeks approval commercially to market the patented product. The Commissioner is given discretion to determine whether the patent in question is eligible for an extension and makes his determination on advice from the agencies. Within 60 days of filing of the application for patent term extension, the Commissioner must notify the Secretary of Agriculture, in the case of animal drugs, or the Secretary of Health and Human Services, in the case of human drugs, that a patent term extension has been requested in order for the Secretary to make determinations as to whether or not the applicant acted with due diligence during the regulatory review period. Should the Secretary find that the applicant did not act with due diligence for the entire regulatory period, effecting a denial of the application, the applicant can request a hearing for a redetermination. The hearing must be granted. If a redetermination is made, then the Commissioner will act to either approve or deny the extension.

Determining the length of a patent term extension

The calculation of the length of regulatory period and the extension term varies with the type of product for which an extension is sought. The regulatory period varies because different products undergo different testing and regulatory procedures.

Essentially, the agency that approved the product or method for which the extension is sought determines the regulatory period. Once the agency has determined the length of the regulatory period, it is reduced by the number of days of the review period that occurred prior to the patent's issuance and the number of days during the review period during which the applicant did not act with due diligence. This reduced sum is then divided in half to obtain the length of the extension period to which the applicant is entitled.

The extension period plus the remaining term of the patent after the regulatory approval is obtained, may not exceed 14 years. In addition, for human drugs, antibiotic drugs, human biological products, medical devices, and food or colour additives requiring FDA

approval, there are further limitations on the length of the extension. For instance, patents issued after September 24 1984 may obtain an extension not exceeding five years. Likewise, any patent issued before September 24 1984 but that did not take the actions specified in the regulations to obtain commercial marketing authorization until after that date, may receive an extension not exceeding five years. Finally, if the patent was issued prior to September 24 1984, and the applicant did take the specified actions to obtain commercial marketing authorization, the extension may not exceed two years.

The restrictions on the length of the extension period for animal drug products and veterinary biological products are similar to those for human drugs. The relevant date in the case of these products is November 16 1988. A patent issued after that date may obtain an extension period not exceeding five years. A patent issued prior to that date, but for which the patent holder failed to take actions to obtain commercial marketing or use authorization, may also obtain an extension of the patent term not to exceed five years. In the case of patents issued prior to that date and for which actions directed at obtaining authorization for commercial marketing or use were taken, the extension may not exceed three years. In no case may the additional exclusion period exceed the date set by a terminal disclaimer.

The USPTO provides charts to assist an applicant in determining the regulatory review period and the additional monopoly period. Two of these, relating to extensions for a human drug product and an animal drug product are reproduced in this article to assist the reader in better understanding the regulatory review period and the method by which an additional exclusion period may be determined.

[TABLE 2: CALCULATION OF LENGTH OF PATENT TERM EXTENSION FOR AN ANIMAL DRUG PRODUCT. See Appendix.]

Private Patent Relief Laws and Other Actions in the US Congress

Private patent relief laws

Congress, through its Constitutional powers over patents, legislatively undertook to extend the length of patent terms from 17 to 20 years when it passed the URAA. The legislation affected all US patents. Since 1808, pursuant to its powers, Congress has been asked to pass private relief bills to extend patent terms where the patent owner has been able to demonstrate extraordinary circumstances. In passing such private relief laws, supporting members cite the extraordinary delays that sometimes occur at FDA in connection with the regulatory approval process for some pharmaceuticals in particular [for example, 141 Cong Rec S 19117 (daily ed December 21 1995) (statement of Sen. Simon)]. Although many patent holders, especially those with pharmaceutical patents, have been successful at garnering support for these private relief laws, they may not be easily obtained.

Because Congressional patent extensions are private in nature, they represent a departure from traditional public policy. The proposals often are met with opposition, both from consumer groups seeking generic forms of patented drugs and from generic drug manufacturers. These private patent laws have been effectively insulated from challenge through their inclusion in larger, generic legislation pending before Congress and are sometimes used by adversaries of the pending legislation to defeat the larger bill.

Proposed legislation in the 104th Congress

At least five bills attempting to effect changes in patent extension provisions were pending in the US Congress at the close of the legislative session this autumn, including S 284 and HR 359 which would change the URAA provisions. At the close of session all bills died and none of the bills had been reported out of committee with the exception of one.

With elections imminent in the US at the date of publication of this article, it is impossible to predict what future actions may be taken by the US Congress to effect changes in patent extension provisions. It is doubtful in 1997 when the new Congress convenes that such provisions would be a priority for the returning and new members. Much of the momentum garnered at changing the URAA provisions had abated before the end of session as lawmakers withdrew their support for the legislation. Future legislation concerning patent term extensions may well depend on how many current members return to Congress after the election and what other issues take the political forefront.

Primary Benefits for Pharmaceuticals

With the exception of those patents that received an extended patent term under the URAA, the primary beneficiaries of the additional exclusionary period provisions remain pharmaceutical and related patents. Although cumbersome in the application process, patent term extensions are not impossible to obtain. Pharmaceutical patents particularly benefit from the fact that the extension provisions that apply to such patents are explicit in defining the steps necessary to acquire the extensions. Additionally, in the US system a patent holder may not be limited by the statutory remedies related to delay in patent approval because of Congress's willingness to fashion private patent law remedies. The continued availability of such private patent laws is affected generally by the political climate and specifically by the patent holder's ability to bring his patent to the attention of lawmakers, however.

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CALCULATION OF LENGTH OF PATENT TERM EXTENSION FOR A HUMAN DRUG PRODUCT			
1. Enter the number of days for the testing phase as defined in 37 CFR 1.775(c)(1)			
2. Enter the number of days for the approval phase as defined in 37 CFR 1.775(c)(2)			
3. Add line 1 and line 2 and enter the total here			
4. Enter the number of days of the period of line 2 which occurred prior to the issue date of the patent			
5. Enter the number of days the period of line 2 during which the applicant failed to act with due diligence as defined in 37 CFR 1.775(d)(1)(ii)			
6. Add line 4 and line 5 and enter the total here			
7. Subtract line 6 from line 3 and enter the difference here (if less than zero enter 0)			
8. Enter the number of days of the period of line 1 which occurred prior to the issue date of the patent			
9. Enter the number of days of the period of line 1 during which the applicant failed to act with due diligence as defined in 37 CFR 1.775(d)(1)(ii)			
10. Add line 8 and line 9 and enter the total here			
11. Subtract line 10 from line 7 and enter the difference here			
12. Enter the number of days from line 1			
13. Enter the number of days from line 10			
14. Subtract line 13 from line 12 and enter the difference here (if less than zero enter 0)			
15. Multiply line 14 by 0.5 (one half) and enter the amount here			
16. Subtract line 15 from line 11 and enter the difference here (if less than zero enter 0)			
17. Enter the original expiration date of the patent			
18. Enter the expiration date of the patent if extended by the number of days on line 16			
19. Enter the date of the FDA (Food and Drug Administration) final approval			
20. Limitation set forth in 37 CFR 1.775(d)(3)			
21. Add the number of years on line 20 to the date on line 19 and enter the revised date here			
22. Enter the earlier date appearing on line 18 or line 21			
23. Enter the original expiration date of the patent (from line 17)			
24. Check one of the following three boxes and enter the listed time period here			
	<input type="checkbox"/> The patent issued after 24/9/84	5 Years	
	<input type="checkbox"/> The patent issued prior to 24/9/84 and no request for exemption as defined in 37 CFR 1.775(d)(6)(i) was filed prior to 24/9/84	5 Years	
	<input type="checkbox"/> The patent issued prior to 24/9/84 and an exemption as defined in 37 CFR 1.775(d)(6)(ii) was filed prior to 24/9/84	2 Years	
25. Add the number of years on line 24 to the date on line 23 and enter the revised date here			
26. Enter the earlier date appearing on line 22 or line 25			
27. Enter the original expiration date of the patent (from line 17)			
28. Enter the number of days by which line 26 and line 27 differ here This is the length of patent term extension			

CALCULATION OF LENGTH OF PATENT TERM EXTENSION FOR AN ANIMAL DRUG PRODUCT					
1.	Enter the number of days for the testing phase as defined in 37 CFR 1.778(c)(1)				
2.	Enter the number of days for the approval phase as defined in 37 CFR 1.778(c)(2)				
3.	Add line 1 and line 2 and enter the total here				
4.	Enter the number of days of the period of line 2 which occurred prior to the issue date of the patent				
5.	Enter the number of days of the period of line 2 during which the applicant failed to act with due diligence as defined in 37 CFR 1.778(d)(1)(ii)				
6.	Add line 4 and line 5 and enter the total here				
7.	Subtract line 6 from line 3 and enter the difference here (if less than zero enter 0)				
8.	Enter the number of days of the period of line 1 which occurred prior to the issue date of the patent				
9.	Enter the number of days of the period of line 1 during which the applicant failed to act with due diligence as defined in 37 CFR 1.778(d)(1)(ii)				
10.	Add line 8 and line 9 and enter the total here				
11.	Subtract line 10 from line 7 and enter the difference here				
12.	Enter the number of days from line 1				
13.	Enter the number of days from line 10				
14.	Subtract line 13 from line 12 and enter the difference here (if less than zero enter 0)				
15.	Multiply line 14 by 0.5 (one half) and enter the difference here				
16.	Subtract line 15 from line 11 and enter the difference here (if less than zero enter 0)				
17.	Enter the original expiration date of the patent				
18.	Enter the expiration date of the patent if extended by the number of days on line 16				
19.	Enter the date of the FDA (Food and Drug Administration) and final approval				
20.	Limitation set forth in 37 CFR 1.778(d)(3)			14 Years	
21.	Add the number of years on line 20 to the date on line 19 and enter the revised date here				
22.	Enter the earlier date appearing on line 18 or line 21				
23.	Enter the original expiration date of the patent (from line 17)				
24.	Check one of the following three boxes and enter the listed time period here				
	<input type="checkbox"/>	The patent issued after 16/11/88	5 Years		
	<input type="checkbox"/>	The patent issued prior to 16/11/88 and no major health or environmental test was initiated and no request for exemption as defined in 37 CFR 1.778(d)(6)(i) was filed prior to 16/11/88	5 Years		
	<input type="checkbox"/>	The patent issued prior to 11/16/88 and an exemption as defined in 37 CFR 1.778(d)(6)(ii) was filed prior to 16/11/88 and commercial marketing or use of the animal drug was not approved prior to 16/11/88	3 Years		
25.	Add the number of years on line 24 to the date on line 23 and enter the revised date here				
26.	Enter the earlier date appearing on line 22 or line 25				
27.	Enter the original expiration date of the patent (from line 17)				
28.	The difference between line 26 and line 27 is the length of patent term extension				

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